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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,807	08/05/2003	Edward Rubenstein	018050-000140US	9762
20350	7590	04/21/2005	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			BIANCO, PATRICIA	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/635,807

Applicant(s)

RUBENSTEIN ET AL.

Examiner

Patricia M Bianco

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-13 and 16-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-35 is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,10-13,16-20 and 23-25 is/are rejected.
- 7) ☒ Claim(s) 8,9,21 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detailed Action.

## **DETAILED ACTION**

### ***Response to Amendment***

1. In the amendment filed 1/19/05, portions of the specification have been amended to obviate drawing objections, a new abstract has been submitted, claims 1, 6, 9, & 13 were amended, claims 3, 4, 14, & 15 were cancelled, and claims 16-35 added. As a result, claims 1, 2, 5-13, & 16-35 remain currently pending.
2. The allowability of claims 1, 2, 13, & 16 has been withdrawn (see rejection below).

### ***Drawings***

3. The drawings were received on 1/19/05. These drawings are approved.

### ***Response to Arguments***

4. Applicant's arguments with respect to claims 1-35 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3762

Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Buchwald et al. (4,610,658). Buchwald et al. teaches of a shunt for implantation in the brain for transferring CSF in hydrocephalus patients (col. 1, lines 44-50). The shunt is implantable and drains fluid from a brain ventricle to another location in the body. The apparatus and method comprises implanting a catheter (11) connected to a pump (13) that has a motor powered by a power source, preferably a battery (col. 6, lines 33-35). Buchwald discloses that the pump may be a diaphragm pump or a piston pump.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 3762

Claims 1, 2, 5-7, 10, 11, 12, 16-20, & 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchwald et al. (4,610,658) in view of Watson (5,387,188). Buchwald et al. teaches of a shunt for implantation in the brain for transferring CSF in hydrocephalus patients (col. 1, lines 44-50). The shunt is implantable and drains fluid from a brain ventricle to another location in the body. The apparatus and method comprises implanting a catheter (11) connected to a pump (13) that has a motor powered by a power source, preferably a battery (col. 6, lines 33-35). Buchwald discloses that the pump may be a diaphragm pump or a piston pump. The pump has a housing defining an inner chamber, which holds a pump drive, which is seen to be hermetically sealed. The pump driver may include electronic controls such as speed controls, timers, memory chips, etc. that allows the driver to automatically function (col. 6, lines 40-58). Buchwald shows two portions of tubing extending from the pump, seen to be equivalent to the ventricular and peritoneal catheters. Buchwald also teaches that the dimensions of the shunt system are not critical and may be sized to meet one's particular needs (col. 8, lines 41-43).

Buchwald substantially teaches the invention as claimed, they do not specifically teach that the shunt or conduit has a first and a second opening. Watson teaches a shunt and method of using said shunt in a CSF shunting process. The shunt comprises a ventricular and a peritoneal catheters (12/28) that are connected in fluid communication to a pump (14/34). The catheters have open lumens and therefore openings at their respective ends. At the time of the invention, it would have been an obvious matter of design choice to modify the ventricular and peritoneal catheters of

Art Unit: 3762

Buchwald to be open lumen catheters as taught by Watson, as a substitution of parts, since applicant has set forth no criticality as to the structure and function of the ventricular and peritoneal catheters having openings or open ends.

With respect to claims 11, 12, 24 & 25 they are rejected as being obvious over Buchwald & Watson. Although Buchwald & Watson substantially teaches the invention as claimed, they do not specifically teach that the length of the ventricular catheter is from 10 cm to 50 cm and the inner diameter between 0.1 mm to 2 mm, nor that the peritoneal catheter have a length of the ventricular catheter is from 25 cm to 125 cm and the inner diameter between 0.1 mm to 2 mm. Buchwald does teaches that the dimensions of the shunt system are not critical and may be sized to meet one's particular needs. Therefore, at the time of the invention, it would have been a matter of obvious design choice, of one having ordinary skill in the art, to modify the length and internal diameter on a case-by-case basis, since each patient, such as based on age or adult vs. child, will require a different size. Further, the modifications based on size are obvious since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

#### ***Allowable Subject Matter***

7. Claims 8, 9, 21, & 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The subject matter of the

Art Unit: 3762

claims could either not be found or was not suggested in the prior art of record. The subject matter not found was the further comprising of a recirculation loop and a valve in the recirculation loop, wherein the valve selectively directs flow to the drainage end of the conduit or to an inlet of the pump, in combination with the other elements (or steps) in the claims.

8. Claims 26-35 are allowed over the prior art. The subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found was the further comprising of a recirculation loop and a valve in the recirculation loop, wherein the valve selectively directs flow to the drainage end of the conduit or to an inlet of the pump, in combination with the other elements (or steps) in the claims.

### ***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 16<sup>th</sup>, 2005

  
**PATRICIA BIANCO**  
**PRIMARY EXAMINER**

Patricia M Bianco  
Primary Examiner  
Art Unit 3762